

REMARKS

The Claim Amendments

The Examiner has withdrawn all rejections based on prior art. Therefore, Applicants have not amended or cancelled claims for the purpose of avoiding the prior art.

Applicants have amended or cancelled claims solely to expedite prosecution and to present the claims in better form for allowance or consideration on appeal. See 37 CFR 1.116. Applicants reserve the right to pursue the claims as previously pending, or claims of similar scope, in this application or in future applications.

Claims 1 and 22 are amended. The amendments do not narrow the scope of the claims. The amendments are supported by the specification and claims as originally filed.

Claim 25 is cancelled.

No new matter is added.

The Rejections

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1, 4-23 and 25 as being indefinite. With respect to claim 1, the Examiner alleges that it is unclear whether the clause “wherein said first antibiotic and second antibiotic can be used for selecting a transformed plant cell” is intended to represent a selection step in the method. The Examiner rejected claims 22 and 23 as allegedly lacking antecedent basis for the phrase “at least one recombinant DNA”. The Examiner provides no discussion of the basis for the rejection of claim 25.

In response, Applicants have amended claims 1, 22 and 23. Claim 25 is canceled.

With respect to claim 1, the claim is amended to clarify that the cited “wherein” clause does not represent a step of the method. The clause provides a characterization of the antibiotics that may be used in the claimed method. Specifically, the first and second antibiotics should be antibiotics that are useful for the selection of transformed plant cells. To make this meaning clearer, the claim is amended such that the clause reads, “wherein said first antibiotic and second antibiotic are characterized in that said first antibiotic and said second antibiotic can be used for

selecting a transformed plant cell”. In addition, this clause is moved from the end of the claim to part (a), where such antibiotics are first mentioned in the claim.

With respect to claims 22 and 23, the claims are amended to explicitly describe the “recombinant DNA” in terms identical to those used in claim 1.

Claim 25 is canceled, and therefore the rejection for lack of clarity is obviated.

Applicants request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Claim rejections under 35 U.S.C. § 112, Enablement

The Examiner rejects claims 1, 4-23 and 25 as allegedly failing to provide enablement commensurate with the scope of the claims. The Examiner believes that the specification is enabling for the detailed protocol set forth in Example 2. The Examiner contends that, regardless of Applicants’ statements in the Amendment of September 29, 2004, the transformation of *Linum usitatissimum* was not well known in the art. The Examiner further contends that the claims omit essential elements, including *Agrobacterium* transformation, use of a selectable marker wherein the DNA confers resistance to a first and a second antibiotic, wherein the second antibiotic is different from the first antibiotic, and wherein the antibiotics are selected from the group consisting of kanamycin, paromycin, neomycin, gentamycin, G-418, streptomycin, spectinomycin and imidazole. The Examiner has rejected claims 22 and 23 for the same reasons as claim 1. The Examiner has rejected claim 25 as allegedly lacking any method steps. Applicants traverse.

The “essential elements” cited by the Examiner are no more than minor variations of the claimed method. As discussed below, one of ordinary skill in the art can readily test such variations using no more than routine experimentation. Accordingly, the claims are adequately enabled.

Contrary to the Examiner’s statements, the specification does teach that the transformation of *L. usitatissimum* was known in the art at the time of filing. The specification cites the following examples of such transformations on pages 1 and 2. Bretagne-Sagnard et al. (1996) used *Agrobacterium tumefaciens* and a spectinomycin selection step to transform

hypocotyl tissue. Bretagne-Sagnard also successfully tested kanamycin and G418 selection markers. See Bretagne-Sagnard, page 133, bottom of the left column through the top of the right column.¹ McHughen and Jordan (1989) used *Agrobacterium tumefaciens* and a kanamycin selection step to transform both cotyledons and hypocotyls. Zhan et al. (1988) used *Agrobacterium rhizogenes* for transformation. Ling (1997) used a protoplast transformation system. U.S. Patent No. 5,973,227, filed May 6, 1998 (not referenced in the specification; cited in the accompanying Supplemental Information Disclosure Statement), describes transformation of flax hypocotyls by particle bombardment, followed by kanamycin selection. With respect to the selection of antibiotics, the 5,973,227 patent recites, “The use of kanamycin as a selective agent has proven to be satisfactory for flax bombarded with the NPT-II gene, but other selectable marker genes and selective agents may be used instead.” Therefore, at the time of filing of the present application, flax transformation techniques were known, and such techniques varied in terms of the mode of transformation (different *Agrobacterium* strains, protoplasts, projectiles), choice of selectable marker (kanamycin, G418, spectinomycin) and target tissue (cotyledon, hypocotyl).

Although methods for flax transformation were known in the art, these methods were not optimal and tended to be inefficient, genotype-dependent, time consuming and, in many cases, resulted in plants with aberrant morphology. See page 2, lines 8-19 of the specification. Therefore, the present disclosure provides an approach for improving flax transformation, regardless of the initial mode of transformation that is employed. The specification states, “One of the most important aspects of the method of the invention is to transfer growing calli or shoots derived therefrom successively from a medium containing a first antibiotic [to] a medium containing a second antibiotic.” See page 3, lines 16-19. In fact, the specification specifically recites that the multiple antibiotic selection methodology may be applied regardless of how the initial transformation was performed. “It is to be understood that the crucial step of the method of the present invention is step (c) [the multiple antibiotic selection]. Therefore, methods starting with plant material wherein plant cells have already been transformed with a

¹ Bretagne-Sagnard also describe unsuccessful testing of paromomycin, however, it appears that only a single concentration was tested and therefore one cannot reach a definitive conclusion regarding the use of paromomycin.

recombinant DNA molecule...are also encompassed by the present invention as long as step (c) described above and further explained below is performed.”

The Examiner has alleged that the claims are lacking certain “essential elements”. However, there is no basis in U.S. patent law for an examiner to identify, without reference to the specification, certain elements as “essential” and require the inclusion of such elements in the claims. The Manual of Patent Examining Procedure (“MPEP”) (8th edition) 2164.08(c), recites:

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended.

The courts concur with the MPEP on this point. In *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317 (Fed. Cir. 2002), the court writes:

In [*Gentry*], we did not announce a new ‘essential element’ test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements...Rather, in *Gentry*, we applied and merely expounded upon the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope.

The specification identifies only the selection of transformants with at least two different antibiotics as a “crucial step”, and this aspect appears in the claims. None of the other features identified by the Examiner constitutes “essential components” because variations in each feature were practiced in the art at the time of filing. Furthermore, given the number of variations already known in the art at the time filing, it would have been a matter of routine experimentation for one of ordinary skill in the art to test other variations.

The Examiner argued that the specific antibiotics to be used in the claimed methods are an “essential element”. However, as noted above, kanamycin, G418 and spectinomycin were all previously known to be effective as selection agents for flax. Therefore, it is clear that the specific agent is not critical to the claimed methods, and furthermore, the specification does not recite any particular agent as being an essential element of the claims. Rather, the important feature is that the selection agent should be one that is appropriate for selection of transformed plants. Given the ease with which those of skill in the art had previously assessed the efficacy of

kanamycin, G418 and spectinomycin, it would have been a matter of routine experimentation for one of ordinary skill in the art to evaluate additional selection agents for use in the claimed methods. Furthermore, the Examiner appears to misunderstand the range of antibiotics that are available for use in plant transformation techniques. The list of such selection agents is quite short, and the list recited in claim 4 represents nearly all of the antibiotics that were in common use for selecting transformed plants at the time of filing. Accordingly, it is appropriate to replace a nearly complete listing of appropriate antibiotics with a single functional description of the common characteristics of such antibiotics.

With respect to claims 22 and 23, these claims are enabled for the same reasons discussed above.

Claim 25 is canceled merely to expedite prosecution and not in acquiescence to the rejection. The cancellation of claim 25 obviates the rejection.

Applicants request reconsideration and withdrawal of the rejections of claims 1 and 4-23 for alleged lack of enablement.

CONCLUSION

For the reasons presented above, Applicants request that the Examiner allow the claims, as amended, to issue. The Examiner may address any questions raised by this submission to the undersigned at 212-596-9000. Applicants hereby request that any fee required, in addition to the fee supplied with the Request for Extension of Time, be charged to Deposit Account No. 06-1075.

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Respectfully submitted,

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